UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,295	11/29/2001	Mark Uden	078883-0134	9537

7590 03/26/2003

Richard M Simkin
Foley & Lardner
Washington Harbour
3000 K Street NW Suite 500
Washington, DC 20007-5109

EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1636	11

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,295	UDEN ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-49 are pending in the present application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-34 and 36, drawn to a retroviral vector comprising a functional splice donor (FSDS) site and a functional splice acceptor (FSAS) site, wherein the FSDS and FSAS flank a first nucleotide sequence of interest (NOI); wherein the FSDS is upstream of the FSAS; wherein the retroviral vector is derived from a retroviral pro-vector; a retroviral particle obtainable from the same retroviral vector; a cell transfected or transduced with the same retroviral vector; the use of the same retroviral vector for the manufacture of a pharmaceutical composition; a retroviral pro-vector corresponding to the same retroviral vector.

Group II, claim 35 and 47, drawn to a delivery system for a retroviral vector comprising a functional splice donor (FSDS) site and a functional splice acceptor (FSAS) site, wherein the FSDS and FSAS flank a first nucleotide sequence of interest (NOI); wherein the FSDS is upstream of the FSAS, wherein the delivery system comprises one or more non-retroviral expression vector(s), adenoviruses, or plasmid(s) or combinations thereof for delivery of an NOI or a plurality of NOIs to a first target cell and retroviral vector for delivery of an NOI or a plurality of NOIs to a second target cell; and a hybrid viral vector system for in vivo gene delivery having the recited characteristics.

Group III, claim 37, drawn to use of a functional intron to restrict expression of one or more NOIs within a desired target cell.

Group IV, claim 38, drawn to use of a reverse transcriptase to deliver a first nucleotide sequence (NS) from the 3' end of a retroviral vector such that a functional intron is created upon transduction.

Group V, claims 39-41 and 46, drawn to a hybrid viral vector system for in vivo gene delivery, which system comprises one or more primary viral vectors which encode a secondary viral vector, the primary vector vector or vectors capable of infecting a first target cell and of expressing therein the secondary viral vector, which secondary vector is capable of transducing a secondary target cell.

Group VI, claim 42, drawn to a hybrid viral vector system wherein the lentiviral vector comprises or is capable of delivering a split-intron configuration.

Group VII, claim 43, drawn to a lentiviral vector system wherein the lentiviral vector comprises or is capable of delivering a split-intron configuration.

Group VIII, claim 44, drawn to an adenoviral vector system wherein the adenoviral vector comprises or is capable of delivering a split-intron configuration.

Group IX, claim 45, drawn to vectors or plasmids based on or obtained from any one or more of the entities presented as pE1sp1A, pCI-Neo, pE1RevE, pE1RevE, pE1HORSE3.1, pE1PEGASUS4, pCI-Rab, pE1Rab.

Group X, claim 48, drawn to a self-inactivating (SIN) retroviral vector comprising a functional splice donor (FSDS) site and a functional splice acceptor (FSAS) site, wherein the FSDS and FSAS flank a first nucleotide sequence of interest (NOI); wherein the FSDS is upstream of the FSAS; wherein the retroviral vector is derived from a retroviral pro-vector; such that a retroviral vector can not be packaged as a result of reverse transcription of the retroviral pro-vector at a target site.

Claim XI, claim 49, drawn to a retroviral vector capable of differential expression of NOIs in target cells substantially as described herein.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The retroviral vector of Group I, the delivery system of Group II, the functional intron of Group III, the reverse transcriptase of Group IV, the hybrid viral vector system of Group V, the hybrid lentiviral vector of Group VI, the lentiviral vector system of Group VII, the adenoviral vector system of Group VII, the vectors or plasmids of Group IX, the self-inactivating retroviral vector of Group X, and the retroviral vector capable of

differential expression of NOIs in target cells of Group XI do not contain the same component(s) or elements(s) among themselves, and therefore they lack the same or corresponding technical features. For example, the delivery system of Group II requires the presence of one or more non-retroviral expression vectors that are structurally or chemically different from the retroviral vector of Group I. Similarly, a functional intron, a reverse transcriptase, a hybrid viral vector system wherein one or more primary viral vectors which encodes a secondary viral vector, a hybrid lentiviral vector system, a lentiviral vector system, an adenoviral vector system, a plasmid vector system, and a self-inactivating vector do not share the same common structural components and therefore common technical features among themselves.

Because these inventions are distinct for the reasons set forth above, it would be unduly burdensome for the examiner to search and/or consider the patentability of all of the inventions in a single patent application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.